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CELERA PHARMACEUTICALS 180 KIMIBALL WAY SOUTH SAN FRANCISCO, CA 94080

In re Application of

Darin A. Allen et al

Serial No.: 09/737,687

Filed: December 14, 2000

Attorney Docket No.: 218

: PETITION DECISION

This is in response to the petition under 37 CFR 1.144, filed February 23, 2004, requesting withdrawal of an improper restriction requirement. The delay in acting on this petition has been occasioned by applicants entitling the petition as a "Reply" rather than as a petition. It is only in the first line of the remarks that the term "Petition" is used.

## **BACKGROUND**

A review of the file history is set forth in a previous petition decision mailed April 28, 2003, and is not repeated here. That decision granted applicants' petition to direct the examiner to examine the full breadth of claim 1, and to not require applicants to restrict the claim to only the examined species (as elected by applicant) and examiner created subgenus based on the species which were determined to be allowable. The examiner was also directed to follow the guidance of M.P.E.P. 803.02 with respect to an election of species in a Markush group.

The examiner prepared and mailed a new non-Final Office action on August 4, 2003, in which a new restriction requirement was set forth. The requirement sets forth a listing of approximately 17 compounds, all of which are N-(4-carbamimidoyl-phenyl)-2-hydroxy-3-XXXXX-benzamides, stating that they are but a sample of the many species encompassed within the claim and provides a classification for each. (Note – XXXXX stands for a ring system such as oxepane, morpholino, thiazinyl, piperazinyl, imidazoyl, etc., or other group, such as carboxy, sulfoxy, etc.) The examiner then stated "The Markush group claimed encompasses a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the other member(s) obvious under 35 U.S.C. 103." (This is the classic Markush group definition. The members of the group are related by a particular function and structure related to that function.) The examiner then required anew an election of a single species within the structure of Formula I, with an exact definition of all variables included for the elected species. The examiner then stated that the elected compound and entire scope of the invention encompassing the elected compound as defined by common classification would be considered.

The examiner also stated that all compounds falling outside the class(es) and subclass(es) of the elected compounds would be considered to be directed to non-elected subject matter and be withdrawn.

Applicants replied on August 29, 2003, electing a species, pointing out where in the specification it could be found and defining all variables of Formula I in relation thereto, as required. The requirement was also traversed with reliance on the same reasons as presented in the previous petition and the directions given in the petition decision.

The examiner mailed a non-Final Office action to applicants on November 19, 2003, summarizing the various points of argument set forth in the traversal of the restriction requirement. The examiner maintained that there is more than one independent and distinct invention claimed and justifies this by reciting various classifications for compounds depending on whether X, X1, X2, X3, and X4 are all carbon or one or more are nitrogen. The examiner also cited burden as a reason for restriction. The examiner then created a (sub)-generic embodiment based on the elected species as shown on page 5 of the Office action and withdraws all other compounds as non-elected. The claims were then objected to as containing non-elected subject matter. No indication of search, examination or Allowability of the elected species or examiner created sub-generic concept was given.

In view of the restriction requirement having been made and repeated this petition was filed.

## DISCUSSION

Applicants petition states, in effect, that the examiner has not followed the direction given in the previous petition decision to examine the full breadth of claim 1, but has instead proceeded in a manner similar to that prior to the first petition decision. The previous decision determined that the Markush group set forth in the generic claim was not improper based on function and structure related to that function.

The examiner again proceeded to require an election of species (although cast as a restriction requirement under 35 U.S.C. 121) and then proceeded to create a subgeneric group based on the species elected by carving it out of the genus. As stated in the previous petition decision, this is not permitted under any section of the statute or Rules of Practice or guidance in the M.P.E.P. It is this specific action which applicants petition most strenuously as being improper, as well as the requirement to then cancel any non-elected subject matter.

Applicants also note that the examiner cites search burden as a reason for restriction. This is a proper reason for restricting between inventions in different statutory classes (e.g. product and apparatus). When, however, an election of species is made, as here, the search burden is reduced to that of a reasonable amount as set forth in M.P.E.P. 803.02 which requires search and examination of the elected species and if found to avoid the prior art an expansion of the search to a **reasonable number of additional species**, not all species. The search burden is, therefore, defined as reasonable. The examiner's previously limited search of only one subclass prior to the first petition decision was not considered reasonable or burdensome.

Further, the examiner's statement that all compounds falling outside the area(s) searched would be considered non-elected invites speculation as to what does and does not fall within the area searched. Considering all the compounds herein claimed, each compound would be classified in a single subclass, but very likely be cross-referenced in numerous other subclasses based on different parts of the structure or functional groups. Considering the structure representing the generic embodiment created by the examiner, the structure must be classified under pyridines, naphthalenes, guanidines, and in many other areas. Assuming that these areas are searched, would structures containing only a pyridine ring be included within the areas searched or not?

## **DECISION**

# The petition is **GRANTED**.

The application will be forwarded to the examiner for examination of claim 1 in its full breadth in accordance with M.P.E.P., as previously directed.

Should there be any questions about this decision please contact William R. Dixon, Jr., by letter addressed to Director, TC 1600, at the address listed above, or by telephone at 571-272-0519 or by facsimile sent to the general Office facsimile number, 571-273-8300.

Bruce M. Kisliuk

Director, Technology Center 1600